Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

Protocol summary

Study aim

The aim of this study will investigate the effect of eight weeks of aerobic exercise on depression, anxiety, and stress in women with hypothyroidism.

Design

41 patients with hypothyroidism will be selected by simple randomization and will be divided into experimental (n=23) and control groups (n = 18).

Settings and conduct

The present study was a semi-experimental study with pre-test-posttest design with control group. The subjects were randomly divided into two experimental groups (23 patients) and control (n = 18) from among the patients referred to Rasoul-e-Akram Hospital in Abdanan city. All subjects participated in this study after informing about the process and the way of doing research and signing written consent. At first, a pre-test was taken from the samples by answering the questions of the DASS-21 questionnaire. The experimental group then participated in an aerobic exercise program for eight weeks, three 60-minute sessions each week. The control group did not participate in any sporting activity properly. After completing the exercise protocol, again, from both groups, the post-test was measured.

Participants/Inclusion and exclusion criteria

Patients with subclinical hypothyroidism can participate in the study, and people with orthopedic problems and heart disease cannot participate in the study.

Intervention groups

Experimental and control groups. The experimental group will participate in an aerobic exercise program for eight weeks, three 60-minute sessions per week. The control group doesn't participate in any sporting activity properly.

Main outcome variables

Depression, anxiety and stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161129031165N3**
Registration date: **2019-08-12, 1398/05/21**
Registration timing: **retrospective**

Last update: **2019-08-12, 1398/05/21**
Update count: **0**

Registration date

2019-08-12, 1398/05/21

Registrant information

Name

Vahid Valiopour Dehnou

Name of organization / entity

Lorestan University

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0086

Email address

valipour.v@lu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

Public title
The Effect of Exercise on Depression, Anxiety, and Stress
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age from 30 to 45 years Consume at least 6 months of Levothyroxine regularly Female gender
Exclusion criteria:
cardiovascular disease and diabetes alcohol and tobacco use Orthopedic problems
Age
From **30 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **41**
Randomization (investigator's opinion)
Randomized
Randomization description
After referring to the Rasool Akram Hospital in Abdanan city, the subjects will be selected based on their availability and after obtaining consent, and using simple randomization method (Flip the coin) assigned into two groups: experimental group (eight weeks aerobic training) and control group (doing daily activities).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Lorestan province, Khorramabad city, Lorestan university of medical sciences
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2017-10-15, 1396/07/23
Ethics committee reference number
IR.LUM.REC.1396.312

Health conditions studied

1

Description of health condition studied
Subclinical Hypothyroidism
ICD-10 code
E02
ICD-10 code description
Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description
Depression
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
Depression, Anxiety and Stress Questionnaire with 21 items

2

Description
Anxiety
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
Depression, Anxiety and Stress Questionnaire with 21 items

3

Description
stress
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
Depression, Anxiety and Stress Questionnaire with 21 items

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The experimental group will participate in an Aerobics exercise program for three sessions (60 min) per week for eight weeks. Both groups will take levothyroxine tablets.
Category
Prevention

2

Description
Control group: Control subjects will not participate in any kind of activity regularly and will only take levothyroxine for 8 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Lorestan
Full name of responsible person
Vahid Valipour Dehnou
Street address
Km 5 of Tehran road - Khorramabad city - Lorestan province
City
Khorramabad
Province
Lorestan
Postal code
44316-68151
Phone
+98 66 3312 0106
Email
valipour.v@lu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan university
Full name of responsible person
Vahid Valipour Dehnou
Street address
Lorestan university, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6815144316
Phone
+98 66 3312 0086
Fax
+98 66 3312 0086
Email
valipour.v@lu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Lorestan university
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Lorestan University
Full name of responsible person
Vahid Valiopour Dehnou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Lorestan University
City
Khorram Abad
Province
Lorestan
Postal code
44316-68151
Phone
+98 66 3312 0086
Fax
+98 66 3312 0088
Email
valipour.v@lu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Lorestan University
Full name of responsible person
Vahid Valiopour Dehnou
Position
Professor
Latest degree
Ph.D.

Other areas of specialty/work
Physiology
Street address
Lorestan University
City
Khorram Abad
Province
Lorestan
Postal code
44316-68151
Phone
+98 66 3312 0086
Fax
+98 66 3312 0088
Email
valipour.v@lu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Lorestan University
Full name of responsible person
Vahid Valiopour Dehnou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Lorestan University
City
Khorram Abad
Province
Lorestan
Postal code
44316-68151
Phone
+98 66 3312 0086
Fax
+98 66 3312 0088
Email
valipour.v@lu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The only consequence of this is the sharing of data
When the data will become available and for how long
Start the access period after printing the results
To whom data/document is available
Researchers
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments